DISCOCERV™

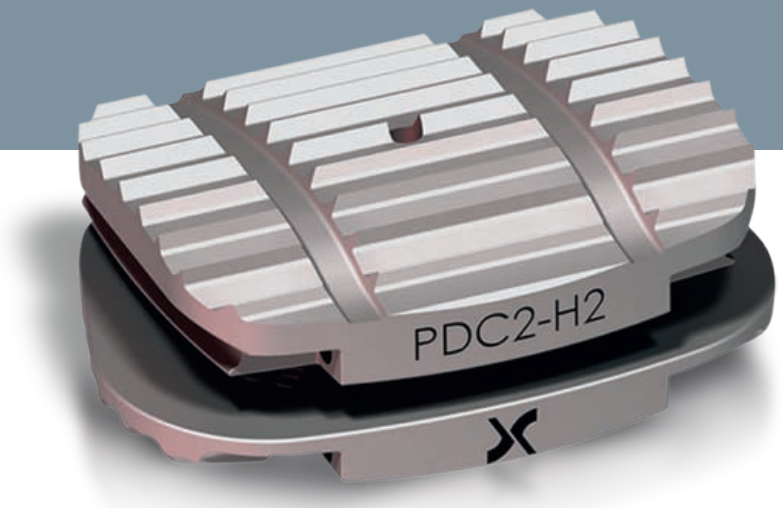
Cervical Disc Prosthesis

SURGICAL TECHNIQUE GUIDE

Scient'x® Alphatec Spine®

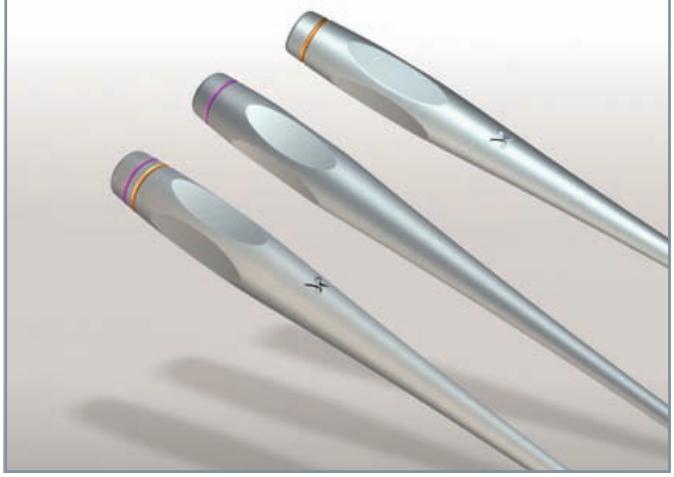
Solutions for the Aging Spine®

Discocerv™: the evolution of the Cervidisc cervical disc prosthesis



Operating time saving

Color coding to optimize instruments identification according to the size of the prosthesis



Optimized design

Convex upper and lower plates to comply with the anatomical curvature of the disc space

Longevity

The plates are made from **titanium** TA6V ELI (ASTM F136 or ISO 5832-3) which gives the prosthesis excellent mechanical and biomechanical properties

The superior ceramic part (convex) is made from **alumina** (AL203 ISO 6474 type A) and the inferior part (concave) from **zirconia** ($ZrO_2HfO_2Y_2O3$ ISO 13356) giving excellent wear resistance in the long term

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

The cervical disc prosthesis DISCOCERV™ – Cervidisc Evolution is a surgical device intended to preserve the physiological mobility of the cervical functional spinal unit via the anterior route.

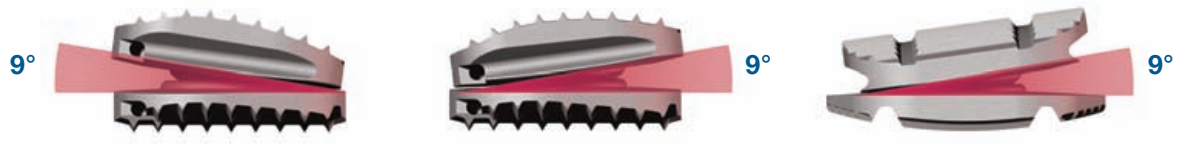
The disc replacement is only indicated for levels from C3 to C7. The main indication is disc degeneration without instability.

The indications include the following :

- degenerative disc disease
- herniated disc
- myelopathy associated with a spondylotic stenosis of the foramen or canal
- root disease associated with a neurological deficiency that does not respond to conservative treatments

Mobility

Angulation of 9° in the sagittal and coronal planes to preserve the physiological amplitude of a normal disc



Security

Bi-directional grooves to avoid antero-posterior and lateral migration of the titanium plates

Controlled movement

Perfect joining of the inferior and superior ceramic parts so as to facilitate prosthesis mobility

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

Pre-operative considerations

Indications :

The DISCOCERV™ cervical disc prosthesis is a surgical implant intended to maintain the physiological cervical mobility of a spinal segment. The prosthesis is implanted between C3 and C7 by the anterior route.

The principal indication is degeneration of the disc without instability. The indications are as follow :

- degenerative disc disease
- herniated disc
- myelopathy associated with a spondylotic stenosis of the foramen or canal
- root disease associated with a neurological deficiency that does not respond to medical treatments

Contraindications :

The contraindications to the cervical disc prosthesis DISCOCERV™ are as follow :

- active infection or local inflammation
- vertebral osteoporosis
- vertebral tumor disease
- injury
- local deformity
- instability
- surgical history at the site to be treated
- rheumatoid arthritis
- metabolic bone disease
- pregnancy
- incompatible age or physical condition of the patient
- obvious lack of mobility at the level concerned
- allergy or intolerance towards the materials constituting the device
- any situation not included in the indications

The DISCOCERV™ cervical disc prosthesis must not be used in the context of disorders requiring a multi-staged arthroplasty or an adjacent arthrodesis (above or below).

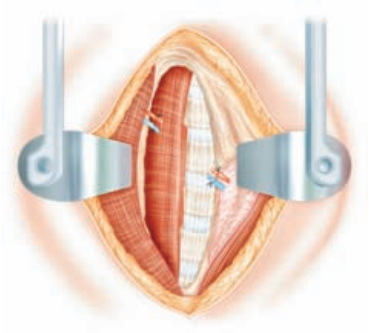
The DISCOCERV™ cervical disc prosthesis is not designed, intended or sold for uses other than those indicated.

Pre-operative X-rays

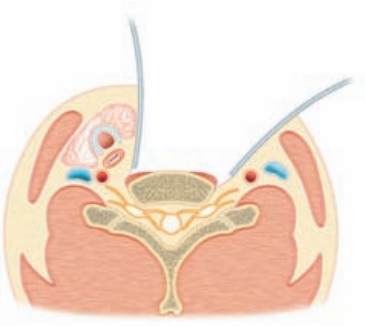
A pre-operative scanner section and profile X-ray should preferably be performed to determine the ideal size of DISCOCERV™ cervical disc prosthesis to be implanted.

1 Surgical protocol/patient positioning

a The surgery should be performed under general anesthesia. The patient should be placed in dorsal decubitus on an ordinary table. The head should be placed in the neutral position (no flexion or hyperextension) ; it may be held in place with an adhesive band. It is vital to keep a strict profile to avoid losing the median line. **The success of surgery depends on this.** It is possible to position the head on a transparent headrest or a transparent extension of the table.



b The approach is a standard right anterior pre-sterno-cleido-mastoid approach (Cloward or Smith-Robinsson).

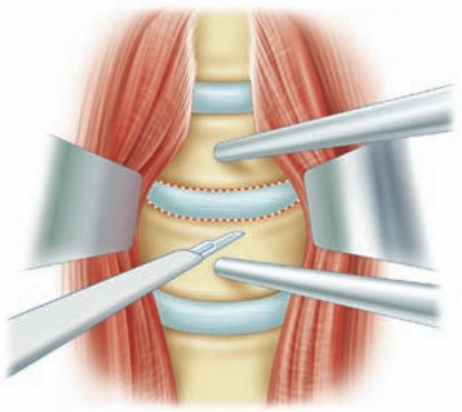


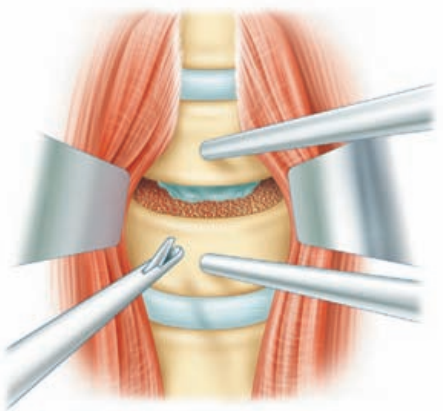
c Under scopic control, determine the correct intervertebral level (image intensifier).

d After incision of the anterior longitudinal ligament, perform the disc resection usingappropriate rongeurs and/or curettes.

2 Discectomy and preparation of the surgical site

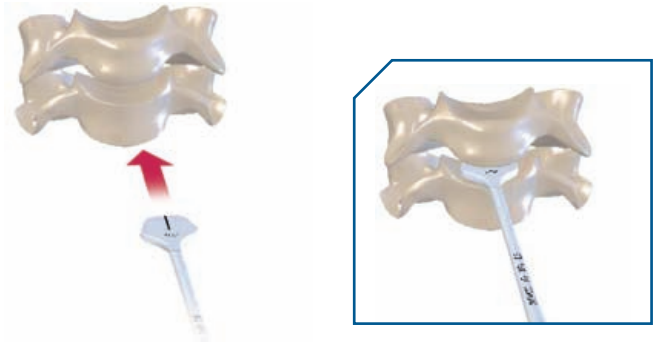
When the disc has been excised, proceed with a bilateral postero-lateral foraminal decompression. If the disc space is too tight, an intersomatic retractor may be used. Decompression may require a high speed drill or a kerisson to free the bone (osteophytosis). This surgical gesture should be performed under surgical microscope.





3 Preparation of the endplates

The vertebral plates should be prepared and cleaned carefully with the curette. A damaged cartilage may cause subsidence of the prosthesis in the vertebral body. This procedure is essential to ensure optimum contact between the implant and adjacent vertebral plates, to avoid secondary displacement.



Note : It is important to insert the two flat probes one after the other to determine the size of the most suitable prosthesis. In order to support a better distribution of the constraints on the vertebral endplates, the prosthesis covering the largest part of the endplate should be chosen.

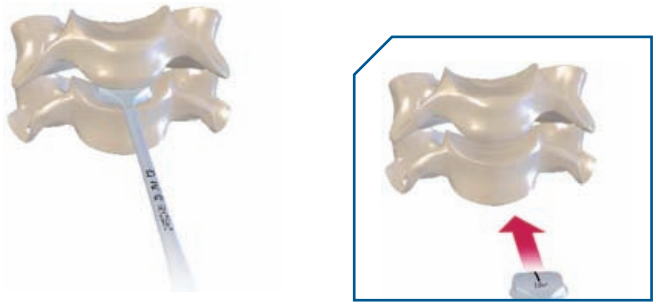
4 Control of the intervertebral space

Once the site preparation is finalized, the **flat probe** should be inserted in the intervertebral space. The flat probe allows to verify the quality of the intervertebral space created after discectomy and select the correct prosthesis footprint.

The flat probes feature a midline laser marking on its superior part that can help to evaluate the midline of the intervertebral space.

Based on this midline laser marking; a marking realized with help of drilling tool, onto the superior and inferior vertebral body can help to keep the midline till the end of the surgery.

The flat probes also feature a color coding helping to identify the prosthesis footprint (Yellow: Small footprint; Purple: Large footprint)



Note : The trials can be introduced and removed easily since their surface have no retaining edges. Trials reflect the height of the implants without teeth.
Trials as flat probes also feature laser marking to identify midline of the intervertebral space

5 Insertion of the prosthesis trials

After selection of the appropriate footprint, the set of **prosthesis trials** must be used to determine the ideal size of the prosthesis to be inserted. The trials also feature the same color coding system as the flat probes, according to the footprint selection in previous step, only the trials following the same color coding will be used. The design of the trials perfectly matches the dimension of the prosthesis without anchoring teeth. The trials are used to determine the implant best suited to the patient's anatomy and requirements.

The choice of the right size of the prosthesis is the most critical part. If the prosthesis is too small, it may migrate and if it is too big, it may interfere with mobility.

Flat probe
21GPC0_

Prosthesis trials
21FPDC_-H_

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

To determine the size of the most suitable implant, it is recommended to first insert the smallest trial implant and sequentially select the next biggest one till the proper size is achieved.

The height to be restored can be determined according to the adjacent disc heights or the facet parallelism at the index level. This is left to the surgeon's discretion.

Following the reference and laser marking indicated onto the trial, the corresponding appropriate prosthesis is selected.

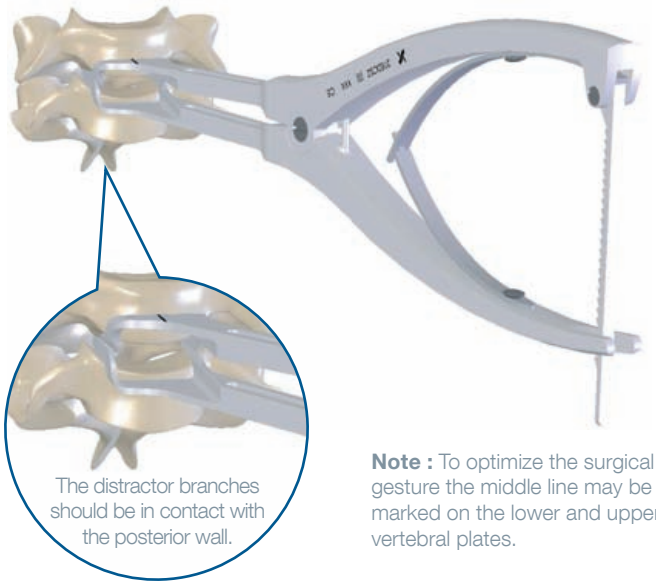
6 Insertion of the cervical distractor

The **distractor** should then be inserted in the intervertebral space. It is recommended to slightly distract the intevertebral space during the prosthesis implantation time. If the anatomy of the patient does not allow the introduction of the specific distractor, a Caspar distractor can be used.

The distractor should be correctly positioned in the transversal plane and should be centered along the midline. The distractor branches should be in contact with the posterior wall.

Scopic control should be performed to ensure correct placement of the distractor:

- frontal control is used to verify correct positioning of the distractor in the transversal plane and exact centering along the midline.
- profile control is used to verify the retraction of the vertebral plates and if needed the retraction of the joint facets.



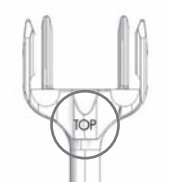
The distractor branches should be in contact with the posterior wall.

Note : To optimize the surgical gesture the middle line may be marked on the lower and upper vertebral plates.

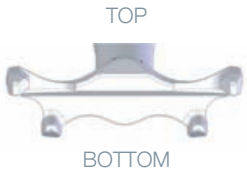
Distractor
21EDC0_

Holder
21PRE0_

TOP VIEW OF THE HOLDER



FRONTAL VIEW OF THE HOLDER

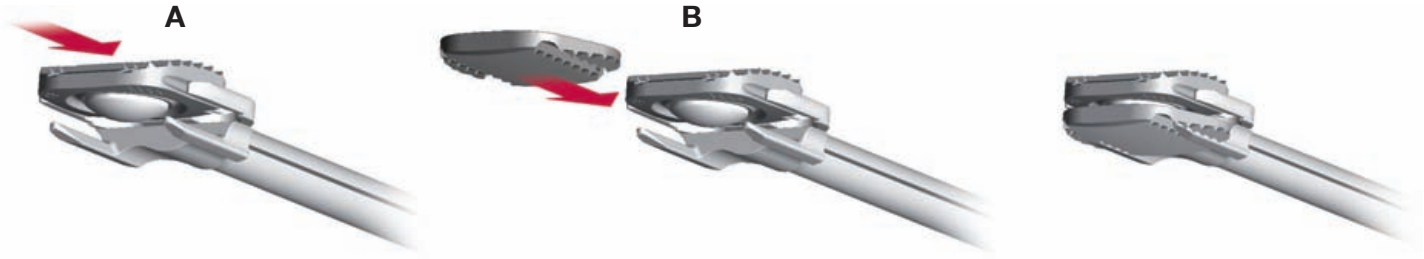


Note : the inscription "TOP" should always be on the top of the instrument

7 Positioning of the prosthesis on the holder

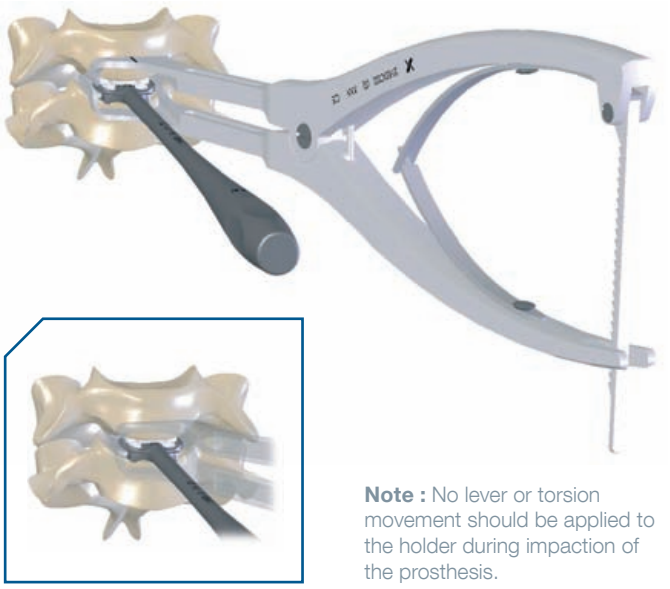
The **holder** is used for impaction of the prosthesis in the intervertebral space. The holder tips fit on the lateral sides of the prosthesis to ensure a firm grasp of the implant.

Firstly, the upper plate (including spherical ball) of the prosthesis is positioned manually (A) on the two upper arms of the holder. The lower plate of the prosthesis is then inserted (B) in the two lower arms of the holder using the flexibility of the instrument.



Note : it is important to obtain a perfect coupling between the two ceramic parts.

Note : To ensure a correct positioning of the implant onto the holder, make sure the frontal part of the prosthesis (including laser marking logo and references) are in contact with the holder. When inserted into the patient, these laser marking logo and references should be visible by the surgeon.



Note : No lever or torsion movement should be applied to the holder during impaction of the prosthesis.

8 Insertion of the prosthesis

The holder takes up little space because it is in line with the prosthesis, leaving the operative zone totally visible. The distractor is used to guide the holder and facilitate visualization of the correct alignment of the prosthesis. The effort during insertion of the prosthesis should be along the ancillary axis.

Superior key
21CLE03 and
21CLE05

Inferior key
21CLE04

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

The posterior edge of the prosthesis must be positionned as close as possible to the posterior wall of the operated vertebrae. That is why it is necessary to correctly prepare the intervertebral space and to remove all osteophytes.

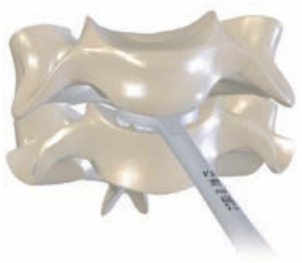
When the prosthesis is in place, the distractor and then the holder may be withdrawn. It is important to check that the prosthesis is correctly placed with a per-operative X-ray.

A proper implant positioning means that the prosthesis is perfectly aligned with the posterior wall.

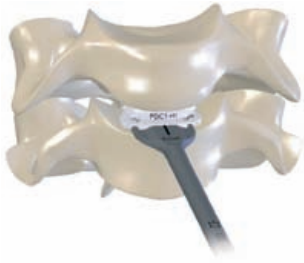
The inferior and superior key can help to adjust the final positioning of the implant.

Note : After scopic control and if necessary, the superior and inferior keys may be used to reposition the prosthesis. For clear identification of the repositioning tool concerning the footprint size, the superior key features the same color coding as previously described (yellow: small footprint; purple: bigger footprint).

SUPERIOR KEY



INFERIOR KEY

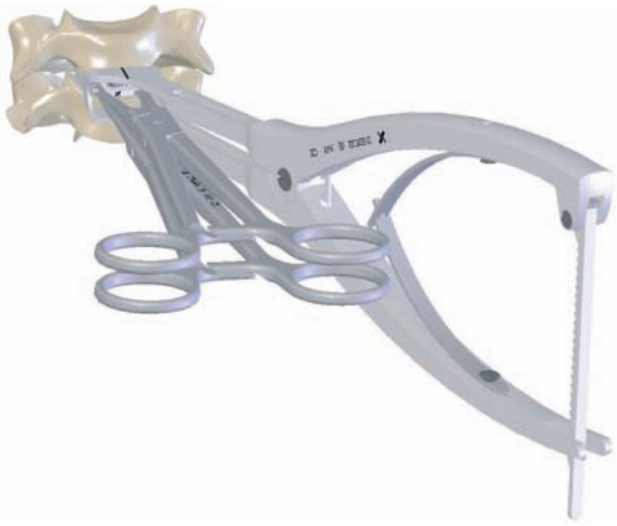


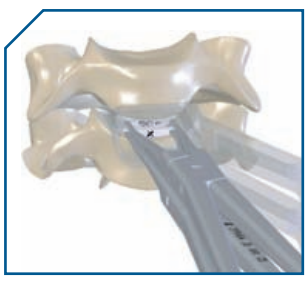
9 Closure of the approach wound

The approach wound is closed after rinsing. Hemostasis is verified and drainage may be required. The platysma should be carefully reconstituted and the skin closed by absorbable intradermic sutures.

Removing the implant

If it becomes necessary to remove the prosthesis, the cervical approach should be performed again until exposure of the instrumented zone. The distractor should be inserted and the **two retrieval keys** placed on the prosthesis to facilitate withdrawal of the implant.





Retrieval key
21PIN04

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

DISCOCERV™

Cervidisc evolution

INSTRUCTIONS, IMPLANTS & INSTRUMENTS

Instruction for use

OBJECTIVE

The Cervical Disc Prosthesis DISCOCERV is an implant intended for the surgical treatment of the cervical spine. The Cervical Disc Prosthesis DISCOCERV is intended for patients suffering from degenerative disorders of the cervical spine, but who do not display any instability.

GENERAL DESCRIPTION

The Cervical Disc Prosthesis DISCOCERV has been designed in order to preserve cervical mobility. The preserved mobility is similar to physiological mobility. **The Cervical Disc Prosthesis DISCOCERV** takes the form of a ceramic joint, consisting of a cup and a spherical ball. The two parts that form the joint are embedded in metal plates that come into contact with the vertebral bodies. The upper surface of the disc replacement inserted into the disc chamber is convex in the sagittal plane, and has a convex profile on its lower surface, in order to match the vertebral plate to the frontal plane as closely as possible. Several different thicknesses are supplied in order to fit different morphologies of the intervertebral spaces. **The Cervical Disc Prosthesis DISCOCERV** is manufactured from ELI titanium (according to ISO5832-3 or ASTM F136), and from two different types of ceramics: zirconia and alumina (ISO 13356 and ISO 6474, respectively). The titanium endplates have been plasma sprayed (with Titanium according to 5832-3 or ASTM F67).

The Cervical Disc Prosthesis DISCOCERV must not be used with components supplied by other manufacturers.

INDICATIONS

The Cervical Disc Prosthesis DISCOCERV is a surgical implant intended to preserve the physiological cervical mobility of a segment of the spine via the anterior route. The disc replacement is only indicated for levels from C3 to C7. The main indication is disc degeneration that does not display any instability.
The indications include the following:

- degenerative disc disease,
- herniated disc,
- myelopathy associated with a spondylotic stenosis of the foramen or canal,
- root disease associated with a neurological deficiency that does not respond to medical treatments.

CONTRAINDICATIONS

The contraindications for the **Cervical Disc Prosthesis DISCOCERV** are as follows:

- active infection or local inflammation,
- vertebral osteoporosis,
- vertebral tumor disease,
- injury,
- local deformity,
- instability,
- surgical history at the site to be treated,
- rheumatoid arthritis,
- metabolic bone disease,
- pregnancy,
- incompatible age or physical condition of the patient,
- obvious lack of mobility at the level concerned,
- allergy or intolerance towards the materials constituting the device,
- any situation not included in the indications.

The Cervical Disc Prosthesis DISCOCERV must not be used in the context of disorders requiring a multi-staged arthroplasty or an adjacent arthrodesis (above or below).
The Cervical Disc Prosthesis DISCOCERV is not designed, intended or sold for any uses other than those indicated.

POSSIBLE SIDE EFFECTS

- infection,
- post-operative migration of the implant,
- spontaneous fusion,
- in cases of fusion affecting the vertebral stages adjacent to the level of the arthroplasty,
- dislocation,
- the plates of the disc replacement may be driven down into the vertebral bodies,
- intolerance towards the material.

Note: An additional surgical operation may be necessary to correct a side effect.

Warnings: Not every surgical operation leads to an entirely satisfactory outcome. This is particularly true of spinal surgery, where numerous external factors can compromise the results.

SURGICAL PRECAUTIONS

The surgeon must be fully conversant with **the Cervical Disc Prosthesis DISCOCERV,** the method of application, the instruments and the surgical procedure. **The Cervical Disc Prosthesis DISCOCERV** must be implanted using the recommended operative technique. The appropriate size of **the Cervical Disc Prosthesis DISCOCERV** must be selected according to the height of the disc to be restored, a height that is inappropriate for the height of the normal interbody space could compromise the clinical outcome.
It is recommended that an intervertebral distractor be used to carry out the discectomy and insertion of the disc replacement. Before implanting **the Cervical Disc Prosthesis DISCOCERV,** the vertebral plates must be carefully prepared by removing the cartilaginous layer and roughening the subchondral bone. It is important not to remove any of the bony endplate as this could lead to subsidence of the Cervical Disc Prosthesis DISCOCERV. Obtaining an absolutely stable primary anchorage of the disc replacement is essential in order to achieve lasting fixation of the implant. The following defects can lead to dislodgement, subsidence and compression of the implant or other post-operative complications:

- excessive removal of bone when preparing the endplate,
- selection of an inappropriate size of disc prosthesis,
- forcible introduction of the replacement, resulting in vertebral fractures,
- be careful to avoid excessive resection of the uncus, which could weaken the vertebral plate.

Secondary anchorage is achieved by means of osteointegration that takes place within the porous structure of the titanium plates of the replacement. This porous structure is obtained by applying a deposit of titanium T40 (ISO 5832-3 or ASTM F67). An X-ray checkup makes it possible to confirm that the cervical disc replacement has been correctly positioned relative to the vertebrae. After the implantation, the **batch number** and the **reference code of the Cervical Disc Prosthesis DISCOCERV** implanted must always be recorded in the patient's surgical file. This can be done using the labels provided inside the sterile packaging.
This product is a single use device. Under no circumstances should it be reused. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for products which have been reused.

Attention: no silicone, formaldehyde or latex based products should be implanted with a SCIENT'X implant.

PACKAGING

Cervical Disc Prosthesis DISCOCERV are supplied in individual sterile packaging. The associated accessory instruments are supplied in a single container, in kit form. The packaging and the kit must be closed, sealed and intact when received. If the depot kit system is used, it is essential to check that it is complete. The condition of all the implants and instruments must always be checked before use. If the kit is to be reassembled in the depot, the implants are supplied in sterile packs, and the instruments in individual sachets. In this case, the labeling shows the reference and batch number of the product, as well as the details of the manufacturer. Instruments supplied in sachets are not sterile.
The storage conditions must be such as to maintain the integrity of the implants, the associated accessories and their respective packaging.
If the packaging ensuring the sterility of the implants has been compromised, or if the implants or accessories have been damaged, the devices concerned must not be used, and should be returned to SCIENT'X.

DECONTAMINATION, CLEANING AND STERILIZATION

Products delivered in sachets are not sterile.

For implants delivered sterile: the implants are sterilized by Gamma radiation at doses of 25 to 40 kGy. The expiry date is 5 years. The expiry date of sterile parts is indicated on the packaging. Re-sterilization of implants delivered sterile is prohibited.

For instruments not sterile on delivery: all instruments delivered non-sterile must be decontaminated, cleaned and sterilized before and after use. Implants and instruments in sachets must be removed from the original packaging for the following operations:

Recommended method:

- **Decontamination:** Plunge the instruments into a bactericidal and fungicidal solution of the didecyldimethylammonium chloride type diluted to 0.5 % (5mL to 1 litre water). Length of soaking: 20 min. Rinse with demineralized water.
- **Cleaning:** Wash the instruments in a LANCER type machine with suitable cleaning products, rinse and dry. Any product that might damage the equipment is forbidden (such as bleach, formol, etc.).
- **Sterilization:** We recommend sterilising the instruments in an autoclave:
  - pre-heating for 25' at 110°C (1 bar)
  - vacuum 5' (0.8 bar under atmospheric pressure)
  - heating 5' at 120°C (1 bar)
  - vacuum 5' (0.8 bar)
  - sterilization 18' at 134°C (2 bars)
  - drying 20' return to room temperature

COMPLAINTS

Any complaints, together with the reference and lot number of the incriminated product, should be sent to Scient'x.

ADDITIONAL INFORMATION

For further information, contact SCIENT'X,
Only for information
Subject to modification without notification
For updated IFU, please contact your local customer service.

Notice d'instructions

OBJECTIF

La prothèse discale cervicale DISCOCERV est un implant destiné aux traitements chirurgicaux du rachis cervical. La prothèse discale cervicale DISCOCERV s'adresse aux patients souffrant d'une pathologie dégénérative du rachis cervical et ne présentant pas d'instabilité.

DESCRIPTION GÉNÉRALE

La prothèse discale cervicale DISCOCERV a été conçue pour permettre de restaurer une mobilité, au niveau cervical. La mobilité restaurée est proche d'une mobilité physiologique.
La prothèse discale cervicale DISCOCERV se présente sous la forme d'une articulation en céramique, composée d'une cupule et d'une sphère. Les deux éléments formant l'articulation sont fixés dans des plateaux métalliques venant au contact des corps vertébraux. La prothèse mise en place dans la chambre discale présente une forme convexe sur sa face supérieure dans le plan sagittal et un profil convexe sur sa face inférieure afin d'épouser au mieux le plateau vertébral dans le plan frontal. Plusieurs hauteurs sont proposées afin de s'adapter aux différentes morphologies d'espaces intervertebraux. **La prothèse discale cervicale DISCOCERV** est fabriquée à partir de titane ELI (selon ISO5832-3 ou ASTM F136), et de ceramique de nature différente Zircone et alumine (respectivement ISO 13356 et ISO 6474). Les plateaux en titane sont recouverts d'un dépôt plasma titane (selon 5832-3 ou ASTM F67).
La prothèse discale cervicale DISCOCERV ne doit pas être utilisée avec des composants provenant d'autres fabricants.

INDICATIONS

La prothèse discale cervicale DISCOCERV est un implant chirurgical visant à restaurer la mobilité cervicale physiologique d'un segment rachidien par voie antérieure. La prothèse ne s'implante qu'entre les niveaux C3 et C7. La principale indication est une dég énérescence discale ne présentant pas d'instabilité.
Les indications comprennent :

- maladie dégénérative du disque,
- hernie discale,
- myélopathie associée à une sténose spondylotique foraminale ou canalaire,
- radiculopathie associée à un déficit neurologique, résistant aux traitements médicaux.

CONTRE-INDICATIONS :

Les contre-indications de **la prothèse discale cervicale DISCOCERV** comprennent :

- infection active ou inflammation locale,
- ostéoporose vertébrale,
- affection vertébrale tumorale,
- traumatisme,
- déformation locale,
- instabilité,
- antécédents chirurgicaux au niveau à traiter,
- arthrite rhumatoïde,
- maladie métabolique osseuse,
- grossesse,
- âge et état physique du patient incompatibles,
- absence manifeste de mobilité du niveau considéré,
- allergie ou intolérance au matériaux constituants le dispositif,
- tout cas non compris dans les indications.

La prothèse discale cervicale DISCOCERV ne doit pas être utilisée dans le cadre de pathologies nécessitant une arthroplastie multi-étagée ou une arthrodèse adjacente (supérieure ou inférieure).
La prothèse discale cervicale DISCOCERV n'est pas conçue, destinée ou vendue pour des utilisations autres que celles indiquées.

EFFETS SECONDAIRES POSSIBLES

- infection,
- migration post-opératoire de l'implant,
- fusion spontanée,
- en cas de fusion atteintes des étages vertébraux adjacents au niveau de l'arthroplastie,
- dislocation,
- enfoncement des plateaux de la prothèse dans les corps vertébraux,
- intolérance au matériel.

Note : Une intervention chirurgicale supplémentaire peut être nécessaire pour corriger un effet secondaire.

Avertissements : Un résultat entièrement satisfaisant n'est pas systématiquement obtenu à chaque opération chirurgicale. Cela est particulièrement vrai en chirurgie du rachis où de nombreux éléments extérieurs peuvent compromettre les résultats.

PRÉCAUTIONS OPÉRATOIRES

Le chirurgien doit être parfaitement familiarisé avec **la prothèse discale cervicale DISCOCERV,** la méthode d'application, les instruments et la technique opératoire. **La prothèse discale cervicale DISCOCERV** doit être implantée conformément à la technique opératoire préconisée.
La taille de **la prothèse discale cervicale DISCOCERV** doit être choisie en fonction de la hauteur discale à restaurer, une hauteur inadaptée à la hauteur de la chambre cervicale peut compromettre le résultat clinique.

Il est recommandé d'utiliser le distracteur intervertébral pour réaliser la discectomie et la mise en place de la prothèse.
Avant implantation de **la prothèse discale cervicale DISCOCERV,** les plateaux vertébraux doivent être curetés soigneusement et avivés sans être fragilisés pour éviter les risques d'enfoncement de **la prothèse discale cervicale DISCOCERV.**
L'obtention d'un ancrage primaire absolument stable de la prothèse est une condition primordiale pour la fixation durable de l'implant. Les défauts suivants peuvent être à l'origine d'un descellement, enfoncement de l'implant ou de toutes autres complication post-opératoires :
- Amincissement excessif de la corticale osseuse lors de la préparation du plateau,
- Sélection inappropriée de la taille de la prothèse,
- Introduction en force de la prothèse entrainant des fractures par éclatement ou un trait de refend osseux,
- Attention au fraisage excessif des uncus de nature à fragiliser le plateau vertébral.

L'obtention d'un ancrage secondaire est autorisé par l'ostéointégration qui prend place dans la structure poreuse des plateaux en titane de la prothèse. Cette structure poreuse est obtenue par la réalisation d'un dépôt de titane T40 (ISO 5832-3 ou ASTM F67).
Un contrôle radiographique permet de constater le bon positionnement de la prothèse cervicale par rapport aux vertèbres.
Après implantation, le **numéro de lot** et **la référence de la prothèse discale cervicale DISCOCERV** implantée doivent **systématiquement** être enregistrés dans le dossier chirurgical du patient. Ceci peut être effectué grâce à l'une des étiquettes disponibles dans l'emballage stérile.
Ce produit est à usage unique. Il ne doit en aucun cas être réutilisé. Bien que le dispositif puisse paraitre en parfait état, il peut présenter de petits défauts ou des contraintes résiduelles résultant d'une utilisation antérieure et pouvant mener à une rupture en fatigue. De plus, veuillez noter que la décontamination des dispositifs réutilisés n'est pas validée et que les dispositifs n'ont pas été conçus en ce sens. La réutilisation d'un tel produit pourrait mener à une contamination croisée et/ou à une dégradation du matériel résultant du procédé de décontamination. Le Fabricant n'accepte aucune responsabilité concernant les produits réutilisés.

Attention : aucun produit à base de silicone, de formaldéhyde ou de latex ne doit être implanté avec un implant SCIENT'X.

■ EMBALLAGE
Les prothèses discales cervicales DISCOCERV sont livrées dans des emballages stériles individuels. Leurs instruments ancillaires associés sont livrés dans un seul conteneur, un « kit ». Les emballages et le kit doivent être fermés, scellés, et intacts à la réception.
Si le système de kit en dépôt est utilisé, la composition complète du kit doit être attentivement vérifiée. Le bon état de tous les implants et instruments doit être contrôlé avant toute utilisation.
En cas de réassortissement de kit en dépôt, les implants sont livrés en boites stériles et les instruments en sachet individuel. L'étiquetage reprend alors la référence et le numéro de lot du produit ainsi que les coordonnées du fabricant. Les instruments livrés en sachets ne sont pas stériles.
Les conditions de stockage doivent permettre de maintenir l'intégrité des implants, des ancillaires associés et de leurs emballages respectifs.
En cas d'endommagement de l'emballage assurant la stérilité des implants ou d'endommagement des implants ou des ancillaires, les dispositifs concernés ne doivent pas être utilisés et doivent être retournés à SCIENT'X.

■ DÉCONTAMINATION, NETTOYAGE ET STÉRILISATION
Les produits livrés en sachets ne sont pas stériles.

Pour les implants livrés stériles : les implants sont stérilisés par rayonnement Gamma à la dose de 25 à 40 kGy. Le délai de péremption est de 5 ans. La date limite d'utilisation des éléments stériles est indiquée sur l'emballage. La restérilisation des implants livrés stériles est proscrite.
Pour les instruments livrés non stériles : tous les instruments livrés non stériles doivent êtres décontaminés, nettoyés et stérilisés avant et après utilisation. Les instruments en sachet doivent être sortis de leur emballage d'origine pour les opérations suivantes :

Méthode conseillée :
- **Décontamination :** Plonger les instruments dans une solution bactéricide et fongicide de type chlorure didécyldiméthylammonium diluée à 0,5 % (5mL pour 1 litre d'eau tiède). Durée du trempage: 20 min. Rincer à l'eau déminéralisée.
- **Nettoyage :** Laver les instruments en machine de type LANCER avec des produits de nettoyage adaptés, rincer, sécher. Tout produit susceptible d'altérer le matériel est à proscrire (eau de javel, formol…).
- **Stérilisation :** Nous recommandons le mode de stérilisation en autoclave pour les instruments :
  - préchauffage 25' à 110°C (1 bar),
  - vide 5' (0,8 bar sous pression atmosphérique),
  - chauffage 5' à 120°C (1 bar),
  - vide 5' (0,8 bar),
  - stérilisation 18' à 134°C (2 bars),
  - séchage 20' retour à l'ambiante.

■ RÉCLAMATIONS
Toute réclamation, accompagnée de la référence et du numéro de lot du produit incriminé, doit être transmise à la société Scient'x.

■ INFORMATIONS COMPLÉMENTAIRES
Pour toute information complémentaire, contactez Scient'x.
Notice à titre informatif.
Sujet à modification.
Notice complète disponible auprès de votre service client.

Istruzioni per l'uso

■ UTILIZZO PREVISTO
La protesi discale cervicale DISCOCERV™ è un impianto destinato al trattamento chirurgico del rachide cervicale. La protesi discale cervicale DISCOCERV™ è destinata a pazienti affetti da disturbi degenerativi del rachide cervicale non accompagnati da instabilità.

■ DESCRIZIONE GENERALE
La protesi discale cervicale DISCOCERV™ è stata progettata per il ripristino della mobilità cervicale. La mobilità così ripristinata risulta simile alla mobilità fisiologica. **La protesi discale cervicale DISCOCERV™** si compone di un giunto in ceramica, composto da una coppa e da una sfera. Le due parti che costituiscono il giunto sono incorporate a placche metalliche che entrano a contatto con i corpi vertebrali. La protesi inserita nello spazio discale presenta una forma convessa sulla faccia superiore sul piano sagittale e ha un profilo convesso sulla superficie inferiore, al fine di corrispondere per quanto possibile al piatto vertebrale sul piano frontale. Sono disponibili diversi spessori in modo da garantire l'adattamento alle varie morfologie degli spazi intervertebrali. **La protesi discale cervicale DISCOCERV™** è prodotta in titanio ELI (conformemente alle norme ISO5832-3 o ASTM F136) e in due tipologie di ceramica: ceramica di zirconia e ceramica di allumina (rispettivamente ISO 13356 e ISO 6474). Il piatto vertebrale in titanio si presenta ricoperto da uno strato di plasma di titanio (conforme a ISO5823-3 o ASTM F67).
La protesi discale cervicale DISCOCERV™ non deve essere utilizzata con componenti di altri produttori.

■ INDICAZIONI
La protesi discale cervicale DISCOCERV è un impianto chirurgico sviluppato per la conservazione della mobilità fisiologica di un segmento del rachide cervicale per via anteriore. La protesi viene impiantata esclusivamente tra i livelli C3 e C7. L'indicazione principale è la degenerazione discale non accompagnata da instabilità.

Le indicazioni includono :
- patologia degenerativa discale,
- ernia del disco
- mielopatia associata a stenosi spondilotica foraminale o canalare
- radiculopatia associata a deficit neurologico non rispondente alla terapia medica.

■ CONTROINDICAZIONI
La protesi discale cervicale DISCOCERV™ è controindicata nei casi seguenti :
- infezione in corso o infiammazione locale,
- osteoporosi vertebrale,
- tumore vertebrale,
- traumi,
- deformità locale,
- instabilità,
- pregressa chirurgia del sito da trattare,
- artrite reumatoide,
- malattie metaboliche dell'osso,
- gravidanza,
- incompatibilità del paziente per età o condizioni fisiche,
- manifesta mancanza di mobilità del livello oggetto di trattamento,
- allergia o intolleranza ai materiali che compongono il dispositivo,
- tutti i casi non previsti nelle indicazioni.

La protesi discale cervicale DISCOCERV™ non deve essere utilizzata nel quadro di patologie che richiedano interventi di artroplastica in più stadi o artrodesi adiacente (superiore o inferiore).
La protesi discale cervicale DISCOCERV™ è stata progettata e prevista per i soli utilizzi indicati e non deve essere venduta per utilizzi differenti.

■ POSSIBILI EFFETTI AVVERSI
- infezione,
- migrazione postoperatoria dell'impianto,
- fusione spontanea,
- in caso di fusione, danni a carico dei livelli vertebrali adiacenti al livello dell'artroplastica,
- lussazione,
- affondamento delle placche della protesi nei corpi vertebrali,
- intolleranza al materiale.

Nota : per la correzione degli effetti avversi potrebbe rendersi necessario un ulteriore intervento chirurgico. Il chirurgo è tenuto a informare il paziente dei possibili effetti avversi.

Avvertenza : Non tutti gli interventi chirurgici si concludono necessariamente con un esito totalmente soddisfacente. Ciò vale in particolare per la chirurgia del rachide, i cui risultati possono essere compromessi da numerosi fattori esterni.

■ PRECAUZIONI CHIRURGICHE
Il chirurgo deve avere maturato una conoscenza approfondita della **protesi discale cervicale DISCOCERV™,** della metodica di applicazione, dello strumentario e della tecnica chirurgica.
La protesi discale cervicale DISCOCERV™ deve essere impiantata ricorrendo alla tecnica chirurgica raccomandata.
La dimensione corretta della **protesi discale cervicale DISCOCERV™** deve essere selezionata sulla base dell'altezza del disco da ripristinare; un'altezza non adeguata rispetto all'altezza del normale spazio tra i corpi vertebrali potrebbe compromettere l'esito clinico.
Si consiglia di utilizzare un distrattore intervertebrale per l'effettuazione della discectomia e per l'inserimento della protesi. Prima dell'impianto di una **protesi discale cervicale DISCOCERV™** sono necessari curettage e cruentazione adeguati dei piatti vertebrali evitando di renderli eccessivamente fragili in modo da evitare il rischio di affondamento della **prothèse discale cervicale DISCOCERV.**
L'ottenimento di un fissaggio primario completamente stabile della protesi è essenziale al fine di conseguire una fissazione duratura dell'impianto. Le difettosità riportate di seguito possono essere causa di affondamento e mobilizzazione dell'impianto o di altre complicanze postoperatorie :
- rimozione eccessiva di corticale ossea nella preparazione del piatto vertebrale,
- selezione di una protesi discale di dimensioni non corrette,
- introduzione forzata della protesi, con conseguente frattura per scheggiamento o scanalatura ossea,
- prestare atenzione a non fresare eccessivamente l'uncus, ciò che potrebbe indebolire il piatto vertebrale.

L'ancoraggio secondario viene conseguito tramite l'osteointegrazione a livello della struttura porosa della placca in titanio della protesi. Tale struttura porosa viene ottenuta con l'applicazione di un deposito di titanio T40 (ISO 5832-3 o ASTM F67).
Un controllo radiografico permette di confermare il corretto posizionamento della protesi discale cervicale rispetto alle vertebre.
Dopo l'impianto, il **numero di lotto** ed il **codice di riferimento** della **protesi discale cervicale DISCOCERV™** impiantata devono sistematicamente essere registrati nella cartella clinica del paziente utilizzando le etichette disponibili all'interno della confezione sterile.
Il prodotto è monouso e non deve in n essun caso essere riutilizzato. Pur risultando apparentemente in perfetto stato, il prodotto potrebbe presentare piccole difettosità o conseguenze di una sollecitazione residua risultante dall'utilizzo precedente che potrebbero comportare la rottura per fatica. Va inoltre tenuto presente che la decontaminazione dei dispositivi riutilizzati non è una procedura convalidata e che i dispositivi non sono stati progettati a tale scopo. Il riutilizzo del prodotto potrebbe essere causa di contaminazione incrociata, mentre la procedura di decontaminazione potrebbe comportare il degrado del materiale. Il Produttore non è responsabile delle conseguenze del riutilizzo di un prodotto.

Attenzione : non utilizzare prodotti a base di silicone, formaldeide o lattice in combinazione con impianti Scient'x.

■ CONFEZIONE
Le protesi discali cervicali DISCOCERV™ vengono fornite in confezioni sterili individuali. Lo strumentario associato viene fornito in un container unico, un "kit". La confezione e il kit devono essere chiusi, sigillati e integri al momento della consegna.
In caso di utilizzo di un kit riassortito da magazzino, verificare attentamente che il kit sia completo. Le condizioni di tutti gli impianti e del relativo strumentario devono sempre essere verificate prima dell'uso. In caso di riassortimento del kit in magazzino, gli impianti vengono forniti in confezioni sterili e lo strumentario viene consegnato in sacchetti individuali. In tal caso, le etichette recano indicazione del codice e del numero di lotto del prodotto, oltre ai dettagli del produttore. Gli strumenti forniti in sacchetti non sono sterili.
Le condizioni di stoccaggio devono garantire l'integrità dell'impianto, dello strumentario associato e delle rispettive confezioni.
Qualora la confezione che garantisce la sterilità dell'impianto non risulti integra, oppure in caso di impianti o accessori danneggiati, i dispositivi in oggetto non devono essere utilizzati e vanno restituiti a Scient'x.

■ DECONTAMINAZIONE, PULIZIA E STERILIZZAZIONE
I prodotti consegnati in sacchetti non sono sterili.

Impianti consegnati sterili: gli impianti vengono sterilizzati a raggi gamma al dosaggio di 25 – 40 kGy. La scadenza è di cinque anni. La data limite di utilizzo dei componenti sterili è indicata sulla confezione. È vietata la risterilizzazione degli impianti consegnati sterili.

Strumenti consegnati non sterili: lo strumentario consegnato non sterile deve essere decontaminato, pulito e sterilizzato prima e dopo l'uso. Impianti e strumenti avvolti in sacchetti devono essere estratti dal sacchetto d'origine procedendo quindi agli interventi riportati di seguito:

Metodica raccomandata:
- Decontaminazione: Immergere gli impianti e gli strumenti in una soluzione battericida e fungicida tipo didecildimetilammonio cloruro diluito allo 0,5 % (5 ml per un litro di acqua tiepida). Durata dell'immersione: 20 min. Sciacquare con acqua demineralizzata.
- Pulizia: Lavare gli impianti e gli strumenti in una macchina di pulizia tipo LANCER con adeguati prodotti di pulizia, sciacquare e asciugare. Non utilizzare prodotti quali varichina o formaldeide che potrebbero danneggiare i materiali.
- Sterilizzazione: Si raccomanda di sterilizzare in autoclave impianti e strumenti secondo la seguente modalità:
  - preriscaldamento: 25' a 110°C (1 bar)
  - vuoto: 5' (0,8 bar a pressione atmosferica)
  - riscaldamento: 5' a 120°C (1 bar)
  - vuoto: 5' (0,8 bar)
  - sterilizzazione: 18' a 134°C (2 bar)
  - asciugatura: 20' ritorno a temperatura ambiente

RECLAMI
I reclami, corredati da riferimento e numero di lotto del prodotto, dovranno essere trasmessi alla società Scient'x

INFORMAZIONI ULTERIORI
Per ulteriori informazzioni, rivolgersi a SCIENT'X.
A solo scopo informativo
soggetto a modifica senza notifica
Per richiedere istruzioni d'uso aggiornate, contattare il Servizio Clienti locale.

Instrucciones de uso

OBJETIVO
La prótesis discal cervical DISCOCERV es un implante destinado a los tratamientos quirúrgicos del raquis cervical. La prótesis discal cervical DISCOCERV va dirigida a los pacientes que padecen una patología degenerativa del raquis cervical y que no presentan inestabilidad.

DESCRIPCIÓN GENERAL
La prótesis discal cervical DISCOCERV ha sido diseñada para permitir restaurar una movilidad a nivel cervical. La movilidad restaurada se acerca a una movilidad fisiológica.
La prótesis discal cervical DISCOCERV se presenta en forma de una articulación de cerámica, formada por una cúpula y una esfera. Los dos elementos que forman la articulación vienen fijados en placas metálicas que se colocan en contacto con los cuerpos vertebrales. La prótesis colocada en el compartimento discal tiene una forma convexa en su cara superior en el plano sagital y un perfil convexo en su cara inferior a fin de unirse de la mejor manera posible con la placa vertebral en el plano frontal. Se ofrecen varias alturas con el fin de adaptarse a las diferentes morfologías de espacios intervertebrales. **La prótesis discal cervical DISCOCERV** está fabricada a partir de titanio ELI (según ISO5832-3 o ASTM F136), y de cerámica de naturaleza diferente a base de Circonio y alúmina (respectivamente ISO 13356 e ISO 6474). Las placas de titanio están revestidas de una capa de plasma de titanio (según ISO5823-3 o ASTM F67).
La **prótesis discal cervical DISCOCERV** no debe ser utilizada con componentes que provengan de otros fabricantes.

INDICACIONES
La **prótesis discal cervical DISOCERV** es un implante quirúrgico cuyo objetivo es restaurar la movilidad cervical fisiológica de un segmento raquídeo por vía anterior. La prótesis sólo se implanta entre los niveles C3 y C7. La indicación principal es la degeneración discal que no presenta inestabilidad.

Las indicaciones incluyen:
- enfermedad degenerativa del disco
- hernia discal
- mielopatía asociada a una estenosis espondilótica foraminal o del canal
- radiculopatía asociada a un déficit neurológico, resistente a los tratamientos médicos

CONTRAINDICACIONES
Las contraindicaciones de la **prótesis discal cervical DISCOCERV incluyen:**
- infección activa o inflamación local,
- osteoporosis vertebral,
- afección vertebral tumoral,
- traumatismo,
- deformación local,
- inestabilidad,
- antecedentes quirúrgicos en el nivel a tratar,
- artritis reumatoide,
- enfermedad metabólica ósea,
- embarazo,
- edad y estado físico del paciente incompatibles,
- ausencia manifiesta de movilidad del nivel considerado
- alergia o intolerancia a los materiales que constituyen el dispositivo,
- cualquier caso no incluido en las indicaciones.

La **prótesis discal cervical DISCOCERV** no debe ser utilizada en el marco de las patologías que requieren una artroplastia multinivel o una artrodesis adyacente (superior o inferior).
La **prótesis discal cervical DISCOCERV** no ha sido diseñada ni está destinada o vendida para usos diferentes a los indicados.

POSIBLES EFECTOS SECUNDARIOS
- infección,
- migración postoperatoria del implante,
- fusión espontánea,
- en caso de fusión, daños en los niveles vertebrales adyacentes a la artroplastia,
- dislocación,
- hundimiento de las placas de la prótesis en los cuerpos vertebrales,
- intolerancia al material.

Nota: Una intervención quirúrgica adicional puede resultar necesaria para corregir un efecto secundario.

Advertencias: No se puede conseguir un resultado totalmente satisfactorio en cada operación quirúrgica. Esto es especialmente cierto en los casos de cirugía del raquis, en los que numerosos elementos externos pueden comprometer los resultados.

PRECAUCIONES OPERATORIAS
El cirujano debe estar perfectamente familiarizado con la **prótesis discal cervical DISCOCERV,** el método de aplicación, los instrumentos y la técnica operatoria. La **prótesis discal cervical DISCOCERV** debe ser implantada conforme a la técnica operatoria recomendada.
El tamaño de la **prótesis discal cervical DISCOCERV** debe elegirse en función de la altura discal que se va a restaurar, pues una altura inadecuada para la altura del compartimento cervical puede comprometer el resultado clínico.
Se recomienda utilizar el distractor intervertebral para realizar la discectomía y la colocación de la prótesis. Antes de la implantación de la **prótesis discal cervical DISCOCERV,** las placas vertebrales deben ser cuidadosamente raspadas y pulidas sin que se vuelvan frágiles a fin de evitar los riesgos de hundimiento de la **prótesis discal cervical DISCOCERV.**
La obtención de un anclaje primario absolutamente estable de la prótesis es una condición primordial para la fijación duradera del implante. Los defectos siguientes pueden ser la causa de un desprendimiento, hundimiento del implante o de cualquier otra complicación postoperatoria:
- Adelgazamiento excesivo de la cortical ósea durante la preparación de la placa
- Selección inapropiada del tamaño de la prótesis
- Introducción forzada de la prótesis provocando fracturas por estallido o una línea de separación ósea
- Cuidado con el fresado excesivo de los uncus susceptible de volver frágil la placa vertebral

La obtención de un anclaje secundario se logra mediante la osteointegración que se produce en la estructura ósea de las placas de titanio de la prótesis. Esta estructura porosa se obtiene mediante el depósito de una capa de titanio T40 (ISO 5832-3 o ASTM F67).
Un control radiográfico permite comprobar el posicionamiento correcto de la prótesis cervical respecto a las vértebras.
Tras la implantación, el **número de lote** y la **referencia de la prótesis discal cervical DICOCERV** implantada deben ser **sistemáticamente** registrados en el expediente quirúrgico del paciente. Esto puede efectuarse por medio de una de las etiquetas disponibles en el embalaje estéril.
Este producto es de un solo uso. No debe en ningún caso ser reutilizado. Aunque pueda parecer que el dispositivo está en perfecto estado, puede tener pequeños defectos o tensiones residuales debido a un uso anterior y pueden provocar una ruptura por fatiga. Además, sírvase constatar que la descontaminación de los dispositivos reutilizados no está validada y que los dispositivos no han sido diseñados en ese sentido. La reutilización de un producto como este podría provocar una contaminación cruzada y/o una degradación del material como consecuencia del procedimiento de descontaminación. El Fabricante no asumirá ninguna responsabilidad relacionada con los productos reutilizados.

Atención: No se debe implantar con un implante SCIENT'X ningún producto a base de silicona, formaldehído o látex.

EMBALAJE
Las **prótesis discal cervicales DISCOCERV** se suministran dentro de unos embalajes estériles individuales. Su instrumental asociado se suministra en un solo contenedor, un "kit". Los embalajes y el kit deben estar cerrados, sellados e intactos en el momento de su recepción.
Si se utiliza el sistema de kit en depósito, se debe verificar atentamente la composición completa del kit. Antes de su utilización, se debe controlar el buen estado de todos los implantes e instrumentos. En caso de reposición de productos de un kit en depósito, los implantes se suministran en cajas estériles y los instrumentos en bolsa individual. El etiquetado recoge entonces la referencia y el número de lote del producto así como las coordenadas del fabricante. Los instrumentos suministrados en bolsas no son estériles.
Las condiciones de almacenamiento deben permitir mantener la integridad de los implantes, del instrumental asociado y de sus respectivos embalajes.
En caso de daño en el embalaje que garantiza la esterilidad de los implantes, o de daño en los implantes o en el instrumental, los dispositivos afectados no deben ser utilizados y deben ser devueltos a SCIENT'X.

DESCONTAMINACIÓN, LIMPIEZA Y ESTERILIZACIÓN
Los productos suministrados en bolsas no son estériles.

Para los implantes suministrados estériles: los implantes han sido esterilizados por radiación Gamma en dosis de 25 a 40 kGy. El plazo de caducidad es de 5 años. La fecha límite de utilización de los elementos estériles viene indicada en el embalaje. Queda excluida la reesterilización de los implantes suministrados estériles.

Para los implantes e instrumentos suministrados no estériles: todos los implantes e instrumentos suministrados no estériles deben ser sometidos a descontaminación, limpieza y esterilización antes y después de su utilización. Los implantes e instrumentos en bolsa deben sacarse de su embalaje original para las siguientes operaciones:

Método aconsejado:
- **Descontaminación:** Sumergir los implantes y los instrumentos dentro de una solución bactericida y fungicida tipo cloruro de didecyldimethylammonium diluida al 0,5% (5mL por 1 litro de agua templada). Duración de la inmersión: 20 min. Enjuagar con agua desmineralizada.
- **Limpieza:** Lavar los implantes y los instrumentos a máquina del tipo LANCER con productos de limpieza adecuados, enjuagar y secar. Se debe excluir cualquier producto susceptible de alterar el material (lejía, formol…).
- **Esterilización:** Recomendamos el modo de esterilización en autoclave para los implantes y los instrumentos:
  - precalentamiento 25' a 110ºC (1 bar)
  - vacío 5' (0,8 bar bajo presión atmosférica)
  - calentamiento 5' a 120ºC (1 bar)
  - vacío 5' (0,8 bar)
  - esterilización 18' a 134ºC (2 bar)
  - secado 20' vuelta a la temperatura ambiente

RECLAMACIONES
Toda reclamación, acompañada de la referencia y del número de lote del producto incriminado, deberá ser transmitida a la sociedad Scient'x.

INFORMACIÓN COMPLEMENTARIA
Para cualquier información complementaria, póngase en contacto con SCIENT'X.
Para información soló
Puede ser modificado sin notificación
Para instrucciones de uso actualizados, contactad el atención al cliente local

Additional informations / Renseignements / Ulteriori informazioni / Información complementaria

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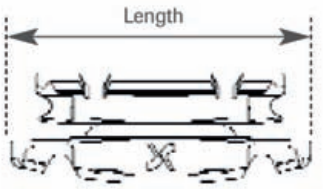
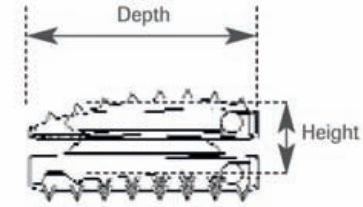
Only for information. Subject to modification without notification.
For updated IFU, please contact your local customer service.

Date of revision : 06/2010

> ALL IMPLANTS ARE DELIVERED **STERILE.**





Discocerv™ prosthesis

Height (mm)	Length (mm)	Depth (mm)	Reference
5.25	17	13	11PDC1-H1S
6			11PDC1-H2S
6.75			11PDC1-H3S
7.5			11PDC1-H4S
6	20	15	11PDC2-H1S
6.75			11PDC2-H2S
7.5			11PDC2-H3S
8.25			11PDC2-H4S

Trials for Discocerv™ prosthesis

	Height (mm)	Reference
11PDC1-H1S	5.25	21FPDC1-H1
11PDC1-H2S	6	21FPDC1-H2
11PDC1-H3S	6.75	21FPDC1-H3
11PDC1-H4S	7.5	21FPDC1-H4
11PDC2-H1S	6	21FPDC2-H1
11PDC2-H2S	6.75	21FPDC2-H2
11PDC2-H3S	7.5	21FPDC2-H3
11PDC2-H4S	8.25	21FPDC2-H4

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

Flat probe for 11PDC1-H_	21GPC01
Flat probe for 11PDC2-H_	21GPC02

Distractor for 11PDC1-H_	21EDC02
Distractor for 11PDC2-H_	21EDC03

Holder for 11PDC1-H_	21PRE08
Holder for 11PDC2-H_	21PRE09

Inferior key	21CLE04

Superior key for 11PDC1-H_	21CLE03
Superior key for 11PDC2-H_	21CLE05

Retrieval key	21PIN04

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

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This product is not available for sale in the United States of America
Non contractual pictures.
Please read carefully the instructions for use bulletin.
Devices may be subject to modification. Patented.

Scient'x® Alphatec Spine®

Solutions for the Aging Spine®

DOMKT504 revision 1.1/ DMQ #: 11-421/Approval date: August 2011